REMARKS

Status of Claims

Claims 2-10, 12-19, and 22-31 were pending. New claims 32-36 are added by this paper. No new matter is entered.

Finality of Office Action

The Office Action mailed May 26, 2005 was marked "Final" on the Summary page, but the Detailed Action made no reference to the Action's having been made final. Moreover, Applicant's prior amendment was made solely to place in condition for allowance those claims the Examiner had already indicated were allowable. So the new grounds of rejection made in the May 26 Office Action cannot be considered to have been necessitated by the prior amendment.

Accordingly, Applicants request that the finality of the May 26 action be withdrawn and/or that the present amendment be entered in the case.

Claim Rejections - 35 U.S.C. § 103(a)

Claims 2-10, 12-19, and 22-31 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Pat. No. 5,438,128 to Nieuwkerk et al. in view of U.S. Pat. No. 5,057,438 to Imai et al.

Applicant respectfully asks the Examiner to reconsider and withdraw the rejection for a number of reasons, given below.

1. <u>There is no motivation to combine Nieuwkerk and Imai.</u>

In setting out the prima facie case, the Examiner acknowledged that Nieuwkerk does not teach a multilayer testing column having plurality of substrates each carrying a different anti-analyte. The Examiner stated, however, that Imai provides this missing

element, and that it would have been obvious to one of ordinary skill in the art to modify Nieuwkerk in the manner of Imai so that Nieuwkerk's device includes a plurality of substrates each carrying a different anti-analyte (i.e., Imai's antigens).

Applicant respectfully asks the Examiner to reconsider and withdraw the rejection, because Nieuwkerk, when considered in its entirety, teaches away from including different anti-analytes in a single device. Instead, the Nieuwkerk patent expressly teaches that its device is designed to test for one analyte at a time. *See* col. 8, lines 15-20:

> Further, the devices can be regenerated and reused multiple times for purification of like samples, but are designed to be disposable when different samples of interest are being investigated. The disposability aspect of the devices eliminate the possibility of cross contamination during the purification process.

As discussed in M.P.E.P. § 2141.02, "[a] prior art reference must be considered in its entirely, i.e., as a <u>whole</u>, including portions that would lead away from the claimed invention" (emphasis in original). *Accord W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 U.S.P.Q. 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984). Moreover, references cannot be combined when they teach away from their combination. M.P.E.P. § 2145(X)(C)(2) ("It is improper to combine references where the references teach away from their combination") (citing *In re Grasselli*, 713 F.2d 731, 743, U.S.P.Q. 769, 779 (Fed. Cir. 1983).

Nieuwkerk teaches away both from both the claimed subject matter and from combination with Imai. Nieuwkerk is concerned that using a single device to test for multiple analytes will cause cross-contamination. Thus, Nieuwkerk, when considered as a whole, teaches away from the concept of a plurality of substrates each carrying a different

anti-analyte. Such a modification would contradict Nieuwkerk's express instruction that only one analyte at a time is to be investigated.

As a result of Nieuwkerk's "one analyte only" teaching, one of ordinary skill in the art would have been discouraged from modifying Nieuwkerk in the manner the Examiner asserts, namely, to provide a plurality of substrates each carrying a different anti-analyte. Any teaching in Imai of providing different anti-analytes is irrelevant in the face of Nieuwkerk's express teaching to test only one analyte at a time. For these reasons, it would not have been obvious to combine the teachings of Nieuwkerk and Imai to reach the subject matter of claim 1.

Analogous arguments apply as well to the subject matter recited in the other independent claims.

2. Nieuwkerk, alone or in combination with Imai, does not teach every limitation of every claim.

All claim elements must be taught or suggested by the prior art in order to establish a prima facie case of obviousness. M.P.E.P. § 2143.03. The references cited in the rejection, taken either alone or together, do not meet this "all elements" requirement.

A. Nieuwkerk does not disclose membranes that are transparent to light or that are substantially transparent to light of at least a selected wavelength.

The Examiner stated that "it would appear that [Nieuwkerk] has the same properties of the instant membrane, i.e. transparent properties" because Nieuwkerk discloses that its membranes are made of cellulose, polyvinylidene fluoride, and nylon, which are disclosed in the present application as materials suitable for making transparent membrane layers.

Applicants ask the Examiner to reconsider the rejection because Nieuwkerk does not suggest in any way that its membranes are transparent. Indeed, Nieuwkerk does not discuss optical properties of its materials at all, probably because Nieuwkerk's device is used solely for purification, not for detection.

The mere fact that Nieuwkerk discloses materials that *might* be used to make transparent layers does not mean that they are necessarily so used. Cellulose, polyvinylidene fluoride, and nylon are all routinely used to make nontransparent articles. See, for example (emphasis added):

> U.S. Pat. No. 4,242,298, col. 1, l.29-31 ("The separated sample is detected by a chemical staining process to yield colored bands or spots on a white, ***opaque, cellulose*** acetate membrane background.")
>
> U.S. Pat. No. 6,562,178, col. 4, l. 28-30 ("Film substrates such as ***opaque polyvinylidene fluoride*** and white polyester are also among those that are suitable for this purpose.")
>
> U.S. Pat. No. 5,551,464 col. 4, l. 36-38 ("In an alternate embodiment, the translucent nylon outside layer 36, metallic middle layer 38, and ***opaque nylon*** inside layer 41 are all laminated together...")

In contrast, claims 3, 4, 19, claims dependent thereon, and claims 27-29 expressly recite devices having membrane layers with some degree of transparency. Because Nieuwkerk does not teach or suggest transparent membranes, and because the membrane materials described in Nieuwkerk are equally capable of being opaque, the "transparent" claim limitations are not met by Nieuwkerk. (All other pending claims lack a "transparent" limitation and should not have a transparency limitation read into them.)

Furthermore, Imai includes no discussion of cellulose, polyvinylidene fluoride, nylon, nor of any material that is necessarily transparent. Even if Nieuwkerk and Imai are combined, then, they still do not meet the "transparent" limitations of claims 3, 4, 19, claims dependent thereon, and claims 27-29.

B. Neither Nieuwkerk nor Imai discloses the light-shielding layers recited in claims 5 and 25, the absorption sub-layers recited in claims 6 and 28, or the light-reflection sub-layers recited in claims 7 and 29.

Claims 5, 6, 7, 25, 28, and 28 specify that one or more membrane layers includes a light-shielding layer. Claims 6 and 28 further require that at least one light-shielding layer includes a light absorption sub-layer, and claims 7 and 29 further require that at least one light-shielding layer includes a light reflection sub-layer. Neither Nieuwkerk nor Imai discuss any such structures. Accordingly, the subject matter recited by these claims is not met by Nieuwkerk and Imai, taken singly or in combination.

C. Neither Nieuwkerk nor Imai discloses the blocking substance recited in claims 8, 9, 23, 24, and 30.

Claims 8, 23, and 30 recite columns in which "at least a plurality of the solid-phase substrates carry a block substance," while claims 9 and 24 further require that "substantially all surfaces within the chamber carry a blocking substance." Neither Nieuwkerk nor Imai discuss blocking. Accordingly, the subject matter recited by these claims is not met by Nieuwkerk and Imai, taken singly or in combination.

D. Neither Nieuwkerk nor Imai discloses the methods of manufacture recited in claims 20 and 21.

Claims 20 and 21 recite preparing columns by stacking and cutting a plurality of sheets. Neither Nieuwkerk nor Imai discuss this manufacturing process. Accordingly, the subject matter recited by these claims is not met by Nieuwkerk and Imai, taken singly or in combination.

E. Neither Nieuwkerk nor Imai discloses the methods of use recited in claims 33 and 34.

Claims 33 and 34 are drawn to methods of analyzing a fluid sample by, among other things, introducing the fluid sample into a multi-layer column as defined by claim 3, and detecting the presence of the analyte in the multi-layer column. While Nieuwkerk describes introducing a fluid sample into a multi-layer column, it does not describe detecting the presence of an analyte in the column (and it does not describe a column as defined by claim 3). The only uses described by Nieuwkerk involve allowing a substance to bind to a membrane and then recovering that substance from the membrane by flushing it out with an elution buffer. *See* Nieuwkerk, col. 4, lines 18-55, especially lines 37-39. That is, Nieuwkerk is used only for purification, not for detection. Imai cannot be combined with Nieuwkerk, for the reasons discussed above.

Applicant accordingly requests reconsideration and withdrawal of the rejection of claims 2-10, 12-19, and 22-31.

Examination of claims 20, 21, 33, and 34

Claims 20 and 21 were deemed withdrawn as directed to an unelected rejection. In response, Applicant asks the Examiner to reconsider this position.

A restriction requirement is not appropriate in this case because the method claims depend from allowable device claims and thereby qualify to be examined in the present application, as set forth in M.P.E.P. § 821.04:

> Where the application as originally filed discloses the product and the process for making and/or using the product, and only claims directed to the product are presented for examination, when a product claim is found allowable, applicant may present claims directed to the process of making and/or using the patentable product by way of amendment.

When the process claims include all the limitations of the allowable product claims, the applicant is allowed to obtain both types of claims in a single patent. This is because the process claims have all of the limitations of the product claims and so cannot be rejected over prior art if the product claims are patentable. *In re Brouwer*, 77 F.3d 422, 37 U.S.P.Q.2d 1663 (Fed. Cir. 1996); *In re Ochiai*, 71 F.3d 1565, 37 U.S.P.Q.2d 1127 (Fed. Cir. 1995).

In this case, the application discloses the claimed products and the claimed methods of using the product. The method claims depend from allowable claims 3 or 19, so it is appropriate for Applicant to present them in a single application.

For these reasons, Applicant asks that claims 20, 21, 33, and 34 be joined in the application.

Respectfully submitted,

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